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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,185	12/29/2000	Nicholas Hunt	P66036US1	5831

7590 06/30/2004

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/750,185

Applicant(s)

HUNT, NICHOLAS

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 237-278 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 237-278 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/673,257.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 18, filed 03/08/04. Office apologized that there is the typographic error for writing the previous pending claims as 1-125, which should be corrected as 1-126. Applicants filed amendment to cancel the claims 1-236, and filed new claims 237-278. Now, claims 237-278 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 237-278 are still vague and indefinite for recitations of “a fragment” and “derivatives” in new claims 237, 240, 241, 251, 254, 255, 265, 268 and 269.
2. Applicants traverse the rejection and submit that the usage of “ fragment” and “derivatives” are common for a person skilled in the art. The broadness of explanation of the claims does not render the claims indefinite. Further, Applicants give a several explanations of the recited “fragment” and “derivatives”, which are only presented in this response.
3. Applicants’ argument has been fully considered; however, it is not persuasive to overcome the rejection. While the explanations of “fragment” and “derivatives” presented by applicants in this response are expectable. However, these definitions or explanations are not described in the specification. The scope of the “fragment” and “derivatives” can be explained as small as two amino acids from the cited G-protein coupled receptor or retroviral capsid protein. Therefore, the question is whether the two amino acids residues are intended or five amino acid residues are intended?
4. MPEP 3173.02 cites: If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid

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infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

5. Because the specification lacks of teaching what the claimed “fragment” and “derivatives” are, the claims also fail to define what the functions of “fragment and derivatives” are, a person of ordinary skill in the art could not interpret the metes and bounds of the claims. The rejections are maintained.

Claim Rejections - 35 USC § 112

6. Claims 237-278 are still rejected under 35 U.S.C. 112, first paragraph on the same ground as stated in the previous Office Action. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, which read on using any or all fragment or derivative of a G-protein coupled receptor and retroviral capsid protein to make a two amino make a viral like particle that comprises a target molecule, a complexing component and a signal component, in which the G-protein in the target molecule is associated with a fragment of the G-protein coupled receptor of the complexing component.

7. Applicants traverse the rejection and argue that office does not establish the lack of enablement by merely allegations of undue breadth. Applicants further argue that in order to satisfy the requirements of 112 first paragraph, it is not necessary to embrace in the claims or describe in the specification all possible forms in which the claims principle may be reduced to practice since the skilled artisan is well aware of what is already known in the art. Applicants also submit that the selecting the target sequence is listed in materials and methods on pages 75 and 76. The selection of the retroviral gag-gene sequences, as referenced in public literature and patent applications listed on page 6 and pages 9-13. Therefore, a person skilled in the art will, without undue experimentation use listed references and public genomic databases to obtain those sequences.

8. Applicants' argument has been fully considered; however, it is not persuasive. The specification, especially the above motioned pages has been reviewed, there is no teaching about the structure of any fragment or a derivate of a G-protein coupled receptor or a retroviral capsid

protein is described. As claims drafted, the metes and bounds of claimed fragment and derivatives can be read on any sequences that may be only contains two amino acid residues of a G-protein coupled receptor and a retroviral capsid protein. Therefor it is unpredictable to use those sequences to form a viral like particle in which a G-protein coupled receptor is able to form a dimmer/oligmer with the G protein. Therefore, the rejection is maintained.

9. New Ground Rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 237, 240, 241, 251, 254, 255, 265, 268 and 269 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claims 237, 240, 241, 251, 254, 255, 265, 268 and 269 are directed to a method for making a viral like particle by using a target molecule comprising a fragment, or derivative thereof of G-protein coupled receptor, a complexing component comprising a G-protein, and a signal component comprising a fragment, or derivative of a retroviral capsid protein. However, the specification does not describe what the "fragment or derivative thereof" is. The written description requirement under Section 112, first paragraph, sets forth that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have concluded that the specification must demonstrate that the inventors had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, the disclosure relied upon must convey to those skilled in the art that applicants had invented the

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subject matter claimed. In re Wilder, et al., 222 U.S.P.Q. 369 (C.A.F.C. 1984). In re Werthheim, et al., 191 U.S.P.Q. 90 (C.C.P.A. 1976). In re Driscoll, 195 U.S.P.Q. 434 (C.C.P.A. 1977). Utter v. Hiraga, 6 U.S.P.Q.Zd 1709 (C.A.F.C. 1988). University of California v. Eli Lilly, 1 19 F.3d 1559, 43 U.S.P.Q.Zd 1398 (Fed. Cir. 1997). Amgen Inc. F. Chugai Pharmaceutical Co. Ltd., 18 U.S.P.Q.Zd 1016-1031 (C.A.F.C. 1991). Fiers v. Stzgano, 25 U.S.P.Q.Zd 1601-1607 (C.A.F.C. 1993). In re Bell, 26 U.S.P.Q.Zd 1529-1532 (C.A.F.C. 1993). To fulfill the requirement of written description, the court has decided that a significance of conception and reduction to practice need to be achieved In re Fiers v. That is if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred. The courts have emphasized that the inventor must clearly and unambiguously identify the salient characteristics and properties of any given claimed nucleotide sequence. It is not sufficient to provide a vague reference to the biological activity (or specificity) of any given nucleotide sequence or merely a generic method of obtaining it.

12. In the instant case, the specification only teaches that a method of making a viral like particle by using a full length G-protein coupled receptor fused to a coil-coil sequence, a G protein, and a signal component comprising a retroviral capsid protein. The specification does not show that at the application was filed, a significance of conception and reduction to practice the claimed invention of selecting a fragment or derivative of a G-protein coupled receptor and a retroviral capsid protein and using them to make a viral like particle.

13. 35 USC 112 requires inter alia that “a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention.” Because the materials claimed to be used in the claimed method does not described, Applicants do not have the possession for the claimed method that needs to use a material that is still in question for making a viral like particle.

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Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
June 24, 2004.



JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600